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Emily Messerli

University of Kentucky, messerli.emily@gmail.com

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The document mentioned above has been reviewed and accepted by the student's advisor, on behalf of the advisory committee, and by the Assistant Dean for MSN and DNP Studies, on behalf of the program; we verify that this is the final, approved version of the student's DNP Project including all changes required by the advisory committee. The undersigned agree to abide by the statements above.

Emily Messerli, Student

Dr. Elizabeth Tovar, Advisor

Final DNP Project Report

Use of the AFIX Model to Improve Adolescent HPV Vaccination:

A Pilot Research Study

Emily Messerli

University of Kentucky

College of Nursing

Spring 2017

Elizabeth Tovar, PhD, APRN, FNP-BC - Advisor/Committee Chair

Lynne Jensen, PhD, APRN, FNP-BC - Committee Member

Jessica Murray, DNP, APRN, FNP-BC - Clinical Mentor

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Abstract

Problem: The CDC estimates one person every 20 minutes every day acquires an HPV-related cancer. Kentucky's HPV associated cancer burden is among the highest in the nation. Adolescent HPV vaccination rates in Kentucky are far below HealthyPeople 2020 goals. Barriers are multifaceted and include provider, patient and system barriers. The AFIX model is an evidenced based quality improvement program that addresses key provider barriers. The USPSTF findings identify a gap in the literature related to AFIX methods to improve rates of adolescent vaccines.

Objectives: The purpose of this study was to evaluate the effects of an intervention using the AFIX model and provider education focusing on the HPV vaccine as cancer prevention. Goal: To evaluate provider knowledge & attitudes of the HPV vaccine and evaluate the effects of provider education on vaccine rates. Specific Aims: 1. Evaluate frequency of use of CDC Talking Points (rubric) 2. Evaluate changes in vaccination with use of rubric.

Methods: Utilizing the Assessment Feedback Incentives eXchange (AFIX) model, this quasi-experimental pilot research project included four phases: a retrospective chart review to establish baseline rates of HPV vaccination and a provider survey to identify barriers and facilitators (Phase 1), an educational intervention focused on presenting the HPV vaccine as cancer prevention (Phase 2), a process/outcome evaluation (Phase 3&4) to assess use and feasibility of the CDC talking points rubric and an outcome evaluation to assess any change in vaccine uptake.

Primary outcome variable: adolescents age 11-17, with no prior history of the HPV vaccine receiving at least one dose.

Results: 63 of 100 medical records reviewed met inclusion criteria. 79% of adolescents received one dose of the HPV vaccine at a well-child visit. Only 34% received dose 2, and only 8% received dose 3. Significant demographic findings: older adolescents and non-Hispanics were less likely to initiate HPV vaccine. Provider survey results revealed the most commonly reported barrier at 80% was the HPV vaccine not being required for school entry. Participation in the Vaccines for children (VFC) program was the most commonly reported facilitator at 82%. The post-intervention process evaluation revealed 50% of the providers changed the way they presented the HPV vaccine to parents. None of the providers used the CDC rubric and the most common barrier was not having a copy to refer to. Two-thirds of the providers felt uptake of the vaccine had increased since the 2-dose series introduced. Only 83% offer vaccine to females & males 100% of the time. None of the providers feel the vaccine is accepted 100% of the time.

Summary/Implications: At 79%, the proportion of adolescents at HealthFirst Bluegrass age 11-17 with one dose of the HPV vaccine was above the statewide average of 58%. The proportion with 2 and 3 doses were on par with national averages, but were still below benchmark. Because the baseline rates were just below the 80% goal and the provider surveys revealed the school requirement barrier, the PI chose to shift the focus to a policy intervention at the school level. Using a CDC drafted school nurse letter to parents of adolescents, the PI proposed a new version of the 5th grade letter to be sent to all Fayette county incoming middle school students. The current letter only lists the 2 state required vaccines (Tdap, MCV) and not the third ACIP recommended HPV vaccine. Given the recent change in the ACIP recommendation to a 2-dose regimen for young teens, this provides a prime opportunity to promote the HPV vaccine to Fayette county middle school students and their parents.

Use of the AFIX Model to Improve Adolescent HPV Vaccination:

A Pilot Research Project

Introduction

Rates of Human Papillomavirus (HPV) vaccination in Kentucky (KY) are below the national average. Because of the identified link between provider recommendation and increased rates of HPV vaccination (Smith, Stokley, Bednarczyk, Orenstein, & Omer, 2016), provider-based interventions such as the successful Assessment, Feedback, Incentives and Exchange (AFIX) program should be implemented at the local level. AFIX is a quality improvement program used to raise immunization coverage levels, reduce missed opportunities to vaccinate, and improve standards of practice at the provider level (Centers for Disease Control & Prevention, 2015). The AFIX program is an evidence-based intervention developed by the Centers for Disease Control and Prevention (CDC) which gained recognition after immunization coverage levels in public clinics in Georgia increased from 40% to 91% between 1986 and 2001. Since 1996, this intervention has become a national model program to improve immunization rates (LeBaron et al., 1997). The Community Preventive Services Task Force (CPSTF), a branch of the United States Department of Health and Human Services (US-DHHS), “strongly recommended” assessment and feedback methods such as AFIX in 1999, 2008, and 2015. The task force’s regularly updated systematic review of the literature supports the use of the AFIX model. Specific gaps in the literature identified by the CPSTF include measuring the effectiveness of the AFIX program on adolescent vaccines (CPSTF, 2015). This provides additional support for this pilot practice improvement project.

The following manuscript will include background information on both the HPV disease epidemiology and the historical rates of the HPV vaccine. Additionally, a summary of a focused

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integrative literature review provided the evidence base for the chosen AFIX design and the methods of this pilot research project. The overall objectives and specific aims of the study were based on HealthyPeople 2020 and 2016 Healthcare Effectiveness Data and Information Set (HEDIS) measures for the HPV vaccine. The phases of methodology include a retrospective chart audit, a baseline provider survey and educational intervention, and an outcome evaluation. Specific study barriers and facilitators will follow the chart audit results and data analysis. Finally, the practice and policy implications and areas for future research will conclude the manuscript.

Background

According to the CDC, nearly 39,000 HPV associated cancers occur annually. Approximately 23,000 cases are women and 19,000 are men. Of the HPV-associated cancers, cervical cancer is the most prevalent in women, and oropharyngeal cancers are the most prevalent in men. Nearly 90% of cervical and anal cancers, 70% of oropharyngeal, vaginal and vulvar cancers, and 60% of penile cancers are HPV associated (CDC, 2016). The direct link between HPV and cancer led to the development of the Human Papillomavirus Quadrivalent (Types 6, 11, 16, 18) Vaccine, Recombinant, approved in 2006. Additionally the Human Papillomavirus Bivalent (Types 16 and 18) Vaccine, Recombinant was approved in 2009, and the Human Papillomavirus 9-valent Vaccine, Recombinant was approved in 2014 (U.S. Food & Drug Administration, 2016).

Kentucky has some of the highest rates of HPV associated cancers in the United States. Specifically, Kentucky's oropharyngeal cancer incidence rates rank first in men and third in women. Vaginal and vulvar cancer incidences in KY rank first and second, respectively. Penile

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cancer incidence in Kentucky is second highest in the nation. Lastly, among the most common HPV related cancer, cervical, Kentucky ranks 7th highest in incidence (CDC, 2016). Primary prevention methods such as the HPV vaccine can reduce this disease burden.

In 2006, the HPV vaccine was approved by the U.S. Food and Drug Administration (FDA) and the national Advisory Committee on Immunization Practices (ACIP) recommended the vaccine be administered to females age 11-24. The HPV vaccine originally approved was a three dose series with doses at zero, two, and six month intervals. In 2009, the vaccine was further approved and recommended for administration to adolescent males age 9-26. Most recently in October of 2016, the Quadrivalent and 9-valent vaccines were approved for a reduced two- dose series with the second dose administered six to twelve months after dose one.

Since 2006, the uptake and compliance rates in adolescents have increased slowly, but the vaccines continue to be underutilized. HPV continues to have lower uptake than the Tetanus-Diphtheria-Pertussis (Tdap) and Meningococcal vaccines (MCV). NIS-teen data from 2015 reveal that Kentucky ranks 32nd in the nation in Tdap rates with 84% of adolescents age 13-17 with > 1 dose Tdap, 22nd in the nation in MCV rates with 79% with > 1 dose MCV, and only 57.4% of females and 34.8 % males with > 1 dose HPV. Additionally, the most recent CDC NIS-teen data, released in August of 2016 reveals that Kentucky ranked 47th of 50 states for 2015 in completion of the series or > 3 doses of HPV vaccination in males, with a rate of only 17.1%. Females with > 3 doses are nearly double at 36.2%, and with > 2 doses 42.7% (Reagan-Steiner et al., 2016). The disparity between rates of Tdap, MCV and HPV reveal missed clinical opportunities since all three can be given at the same 11-12 year old well child visit. Methods to increase the uptake of the HPV vaccine have been reported in the literature.

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Evidence base for Intervention

The AFIX program has its roots in the public health clinics of Georgia. In order to increase coverage levels to achieve national immunization goals, the Georgia Department of Public Health initiated a statewide program in 1986 that consisted of annual assessments of immunization records at its public health clinics. Feedback was given to clinic providers and their staff who then devised their own interventions to improve vaccination rates. Program incentives included awards and rankings of clinics by coverage level as well as poster presentations by successful clinics at annual immunization meetings. Other successful strategies included coordinating with Women, Infants, and Children (WIC) Food and Nutrition Service, conducting reminder/recall phone activities, and providing performance feedback to nursing staff. Resulting from these combined efforts were immunization coverage levels in Georgia public clinics increasing from 40% to 91% between 1986 and 2001. This intervention has become a national model program to improve immunization rates (CDC, 2014).

LeBaron (1997) sought to investigate the marked increase in vaccination rates noted over an 8-year period. He investigated the methods used and the outcomes to compare to national averages. From 1988 – 1994 LeBaron was able to show that while Georgia's vaccination rates rose from 53% to 89%, the national average from the National Health Interview Survey (NHIS) database rose from 53% to only 60% showing that the AFIX intervention was effective. The CDC chose to adopt the Georgia model and recommend its use to all states. In 1999, LeBaron expanded his research further to include other states and cities using the AFIX model. He was able to show in four states (Colorado, Iowa, Louisiana and Missouri) and two large cities (Boston and Houston) how use of the AFIX model led to vaccine rate improvements on par with Georgia at five percentage points per year or a total average increase of 20% over four years.

Appraisal of Evidence

Over the past several years as the focus on low rates of HPV vaccination has increased, a few studies correlating the AFIX model with adolescent vaccine rates have been conducted. An appraisal of the evidence was performed by compiling a synthesis table of the studies (see Table 2). These studies were important in elucidating the need for the proposed provider AFIX intervention. Common provider identified barriers such as time to educate, parental resistance and difficulty in discussing HPV as an STI were identified in four of the studies (Bruno et al., 2014; Bynum et al., 2014; Ferrer, H., Trotter, C., Hickman, M., & Audrey, S., 2014; Hull et al., 2014). Perhaps the strongest evidence was the common theme of provider as facilitator in two of the level 1 studies (Jeudin et al., 2014; Rambout et al., 2014) and two other level 4 and 5 studies (Reiter et al., 2014; Thomas, Strickland, Diclemente, & Higgins, 2013). Lastly, there is sufficient evidence supporting the use of the AFIX model to improve rates of adolescent HPV vaccination. Five total studies ranging from levels 2-7 all show statistically significant rate changes after implementation of an AFIX model at the provider level (Gilkey, Moss, et al., 2014; LeBaron et al., 1997; LeBaron et al., 1999a; Moss, Reiter, Dayton, & Brewer, 2012a; Perkins et al., 2015) (see Table 2).

Based on a review of the available literature, there is evidence to suggest that implementation of provider interventions, such as the AFIX model, could improve uptake of the HPV vaccine in adolescents. Part of the HealthyPeople 2020 goals is to have at least 50% of both public and private vaccine providers implement a method to measure their vaccination coverage. The public sector is mandated to do this because they receive funds or vaccine directly from the government. Vaccines for children (VFC) providers have mandated visits with

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Comprehensive Clinic Assessment Software Application (CoCASA) reports with rates of immunization used as feedback.

Purpose

The purpose of this project was to evaluate the impact of a provider-focused educational intervention focusing on HPV vaccine as cancer prevention. Primary outcome variables were 1) adolescents age 11-17 with no prior history of the HPV vaccine initiating the vaccine at a well-child visit and 2) proportion of providers utilizing the CDC Talking Points.

This pilot research project was conducted at an urban health clinic in the southern United States. The specific goal of the project was to increase rates of HPV vaccination among adolescents at the clinics through provider education and use of the AFIX quality improvement model. Specific Aims: 1. Evaluate frequency of use of CDC Talking Points (rubric) 2. Evaluate changes in vaccination with use of rubric. Hypothesis: 1. Educational session will increase use of rubric from 0 to 80% 2. Use of the rubric will increase initiation rates to 80%.

This pilot research project aimed to assist a Health Resources and Services Administration (HRSA) granted primary care organization in the Southeast. Improving rates of adolescent HPV vaccination could fulfill the HealthyPeople 2020 goal of 80% vaccination rates among adolescents. Quality improvement measures such as improving vaccine rates help to fulfill requirements of HRSA grantees.

Methods/Study Design

This quasi-experimental pilot research project design included four phases: a retrospective chart review (Phase 1), an educational intervention (Phase 2), a process evaluation (Phase 3), and an outcome evaluation (Phase 4).

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The retrospective chart review was conducted on patient charts from December 15, 2015 to February 15, 2016. Additionally, a post-intervention retrospective chart review was planned from December 15, 2016 to February 15, 2017. All providers volunteering to participate in the face-to-face educational in-service signed an informed consent prior to participation. The HPV vaccine is ACIP recommended at the 11-12 year old well child visit or on a catch-up schedule. Based on a power analysis of increasing rates from 57% to 80%, the goal was to review at least 100 medical records. The data collected during the chart review included patient age, gender, race, and insurance type. Other data included was if counseling on the vaccine was provided and by whom, if the vaccine was offered, if it was accepted/declined/deferred by the patient, if the series was initiated, and if it was completed. No patient identifying information was included.

All pediatric and family providers practicing in the clinic were asked to participate in the survey and educational session. An email with a survey cover letter was sent to all providers in the clinic. The survey was administered via REDCap, and all survey results were kept anonymous. For the educational session, the PI asked for volunteers and distributed informed consents at a provider staff meeting prior to the scheduled educational session. Participation in the educational session was also voluntary.

Research Procedures

For the retrospective chart review, the PI assessed the FQHC clinic practices regarding HPV vaccine rates. Specifically, the PI examined 100 electronic medical records to assess the proportion of HPV vaccines that were administered to adolescents between 11-17 years of age. The clinic provided a list of patient medical record numbers for patients ages 11-17 that presented to the FQHC clinic for routine well-child exams (V20.2) between December 15, 2015

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and February 15, 2016. No one other than the PI had access to the list of medical record numbers, and the list was kept in a locked file cabinet drawer in the clinic. Only the PI had this key. Once the electronic medical records were accessed, the list of medical record numbers was destroyed per the clinic's HIPAA policy. Participants included all males and females age 11-17 with encounter for a well-child visit with vaccines (ICD-9 codes V20.2, V04.89, V05.8 and CPT code 90649). Patients were excluded if they initiated the HPV vaccine before the current 11-17 year old well-child visit.

Survey/ Educational Intervention

Before initiating the educational phase, an online REDcap survey and cover letter on the HPV vaccine was distributed to all pediatric providers at the clinic via email. An educational session on the CDC Talking Points evidence based rubric was presented at several lunchtime staff meetings to those providers volunteering to participate between December 1st and 15th and completing the informed consent. This educational session was part of the Incentives component of the AFIX program. Providers were then asked to trial use of the CDC script in their adolescent visits.

Process/Outcome Evaluation

To determine feasibility and sustainability of the intervention, anonymous provider surveys sent via REDcap were completed voluntarily two months after the intervention (educational session). Providers were asked to report on whether they are using the CDC talking points, and if so, how often; if not, they were asked to disclose the barriers (see Appendix G).

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The final planned step of this pilot research project was a measurement of the proportion of HPV vaccination rates in 11-17 year olds two months after the intervention. This was to be completed using the same electronic medical record review process and inclusion/exclusion criteria to determine baseline rates of HPV vaccination. One hundred to 200 medical records were originally proposed for the outcome evaluation from December 15, 2016- February 15, 2017. The quantity of records (100-200) was based on the original power analysis to increase the proportion from 57% to 80%. Because the baseline rates were 79%, a revised power analysis indicated that 600 records would be needed to detect a significant change in vaccine rates given the goal of 80%. In two months time 600 well visits for 11-17 year olds would not be generated. Therefore, the outcome evaluation of vaccine rates was not completed.

Data collection/analysis

All data was collected in Redcap, a secure online research database. The database was analyzed using statistical SPSS software version 23.0 using crosstabs with frequencies, percentages and chi-squared analysis. Significant findings were reported at $p \geq .05$.

Results

Retrospective medical record review of 100 electronic medical records revealed the following descriptive data: 63 met inclusion criteria of no prior history of the HPV vaccine; 79% (n=50) initiated/accepted the HPV vaccine; only 34% (n=17) received the 2nd dose, and only 8% (n=4) completed the series with the third dose. Uptake of the HPV vaccine was broken down into the following demographic categories: age, gender, race, ethnicity and insurance coverage (see Table 1). Significant findings included age and ethnicity. Adolescents accepting the HPV vaccine were significantly younger than those who declined to initiate vaccination (M=13.1, SD=2.0 versus M=14.5, SD=2.1; $p = .024$). Non-Hispanics (69%) were significantly

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less likely ($p=0.012$) to initiate the HPV vaccine compared with Hispanics (92%). Gender, race and insurance status were non-significant.

Baseline surveys were distributed to 14 pediatric providers, and 11 providers participated. Questions were posed related to the provider practice of offering the HPV vaccine and provider perception of HPV vaccine uptake. Additional survey questions evaluated provider identified barriers and facilitators to uptake.

A majority of providers or 63% ($n=7$) report offering the HPV vaccine 100% of the time to females and males, 27% ($n=3$) offer females and males the vaccine 75-99% of the time, and just 10% ($n=1$) offer it 50-74% of the time. Provider perception of vaccine uptake by gender was more varied. Only 27% ($n=3$) of providers reported that females initiated HPV vaccine 75-99% of the time, whereas the remaining 73% ($n=8$) reported female uptake as 50-74%. Male uptake of the vaccine was reported as lower, with only 27% ($n=3$) reporting 75-99%, 44% ($n=5$) reporting 50-74%, 18% ($n=2$) reporting 25-49%, and <10% ($n=1$) reporting 0-24% of male uptake (see Tables 2-5).

The most commonly reported barrier by just over 80% ($n=8$) of providers was not having the HPV vaccine as a requirement for middle school entry. Most frequent provider reported facilitators were participating in the VFC program 82% ($n=9$) and having the time to educate patients about the HPV vaccine 73% ($n=8$).

Provider survey results revealed that 50% of providers ($n=3$) changed the way they presented the vaccine, although none of them reported using the CDC Talking Tips. The most commonly reported barrier was not having a copy of the CDC Talking Tips available. Lastly, as discussed previously, the outcome evaluation of a change in vaccine rates was not completed due

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to baseline proportion of 79% with a power analysis of ≥ 600 EMRs needed to detect a statistically significant change to the goal of 80%.

Discussion

Major findings

The retrospective record review revealed that 79% of the FQHC's adolescents age 11-17 with no prior history of the HPV vaccine initiated/accepted the vaccine at a well-child visit. This was just below the goal of 80% based on HealthyPeople 2020 goals. Uptake of doses 2 and 3 were significantly lower at 34% and 8% respectively. Significant demographic correlations included both age and ethnicity. The younger the patient the more likely they were to accept dose 1 of the HPV vaccine. This finding is potentially based on the increase in well child visits at age 11-12 for adolescents to get the school required physical and Tdap and MCV immunizations. This study's results are different from Bynum et al. (2014) and Reiter et al. (2014) who found that older adolescents age 13-14 were more likely to initiate the vaccine. Additionally, Hispanic patients were more likely to accept /initiate the vaccine than non-Hispanic patients. This mirrors the 2015 NIS-teen data revealing Hispanic males & females having higher uptake of the HPV vaccine over non-Hispanics (CDC, 2016). Baseline provider survey results highlighted the barrier of the HPV vaccine not being required for school entry, as well as providers being less likely to offer the vaccine to males over females. The post-intervention survey revealed that 50% of respondents (n=6) changed the way they present the HPV vaccine to patients. None of the providers used the CDC rubric specifically, and the most commonly reported barrier to this was not having a copy of the rubric available.

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Study Barriers/Facilitators

Barriers encountered were mostly logistical in nature. Initially, the PI planned to have an educational session (the study intervention) for all pediatric providers at one or two staff meetings. The pediatric providers work at two main clinics and seven school-based clinics. This group only meets every other month, and the adult providers (not part of the study population) are also at those meetings. Additionally, as part of an accreditation process, this FQHC had an Operational Site Visit (OSV) scheduled in early December, so all staff meetings for the month were cancelled.

Consequently, the intervention phase was several either individual or small group meetings to present the CDC Talking Points rubric. This shift in methodology actually became a facilitator because of the small group or individual environment. Several of the providers were able to verbalize their frustrations at the HPV vaccine not being required for school entry as a significant barrier to the vaccine's uptake. Additionally, the PI was able to review the new Vaccine Information Statement (VIS) with the 2-dose ACIP regimen just released December 2nd, 2016. A few providers were unaware of the 2-dose series until it was presented. The providers at the seven school based clinics were also not together for a meeting during the proposed educational phase of the study. Several, but not all, of the school based pediatric providers completed the online survey. Rather than a face to face educational intervention, the PI distributed the CDC Talking Points rubric and the CDC slide-set to the seven school based providers via email as they were not available in the last two weeks of December because of School Clinic closings.

Other facilitators of this pilot study were guideline based and patient education/ outreach based. At the time of the study intervention (mid-December), the new CDC/ ACIP

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recommendation for a 2-dose regimen for 11-15 year olds was released. The new VIS, dated 12/2/2016, was distributed to providers and nurses, but practice dissemination had not yet occurred. This provided an additional incentive for the PI to encourage providers to recommend the new 2-dose HPV series to adolescents. Additionally, the VFC program distributed large, stand-up life size posters of a boy and a girl with the logo “If there were a vaccine against cancer wouldn’t you give it to me?” At the time of the provider intervention, the two main clinics of the FQHC had these life-size posters in their lobbies. Only one of the school clinics had the posters displayed.

Practice Implications

Based on the results of the medical record review and provider survey, several practice and policy recommendations can be made. Specifically, the provider survey highlighted the perception that males initiate the HPV vaccine less often than females. Implications include the need to make a concerted effort targeting males especially since their rates of cancer are comparable (CDC, 2016). This perception could lead to providers’ hesitation to strongly recommend the HPV vaccine to males as well as females. The objective data from the retrospective record review revealed that males had a slightly higher uptake over females, possibly suggesting recommendation to females should be stronger. Other demographic data that could influence practice habits relate to ethnicity and insurance status. Non-Hispanics and those with Medicaid or no insurance were less likely to initiate the vaccine. The latter group is the population eligible for free vaccine from the VFC program. According to the provider survey of patient facilitators, awareness of the VFC program ranked lowest with only 36% (n=4) of providers believing their patients were aware of the availability of free vaccines. This combination of data indicates a practice gap for promoting patient awareness of the VFC

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program. Another possible area for practice change is EMR prompts or reminders. Only one provider indicated that EMR prompts/ reminders influenced HPV vaccine rates.

Upon review of patients missing the HPV vaccination, a check of the Kentucky Immunization Registry (KYIR) found several records of either HPV vaccine initiation or completion. These records had not been either scanned into the EMR or manually entered as historical into the immunization record. A process recommendation to the clinic manager, CMA's and nurses will be that a designated person check the KYIR weekly for all scheduled well child visits to ensure up to date records.

Policy Implications

According to Bynum et al. (2014) survey results of provider-identified barriers can be utilized in development of interventions to increase vaccination rates. The provider survey results from this study reveal that the lack of a school mandate is a significant barrier. Efforts nationwide to school mandate the HPV vaccine have been poorly received. Unfortunately, in Kentucky there have been several failed legislative attempts for HPV vaccine education or a school mandate for adolescents to obtain the HPV vaccine (National Council of State Legislatures, 2017). To date, only two states and the District of Columbia have a school mandate for the HPV vaccine. While legislation mandating this may not be realistic at this point, an alternate strategy would be to include an endorsement by both the school nurses and principals on the school letters sent home to all incoming middle school students. The CDC as well as the National Association of School Nurses (NASN) have the same adolescent vaccine letter template (see Appendix F) posted as a policy initiative for school districts (CDC, 2016; National Association for School Nurses, 2015). The PI proposed that this letter replace the

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current school letter distributed to all rising 6th graders. The letter currently in use only lists the two adolescent vaccines required by Kentucky Statute (Tdap and MCV), but omits the CDC/ACIP recommended HPV vaccine. A key component of the proposed letter is the focus of the HPV vaccine as cancer prevention. Additional strength to this letter will be the new 2-dose regimen CDC/ACIP approved December 2, 2016 for adolescents age 11-15. The PI amended the CDC letter to include the 2-dose regimen, as the online school letter template did not reflect this change. This letter was proposed to the school district health coordinator in a meeting on February 23, 2017. The district health coordinator approved the nurse and principal letter for distribution this spring and summer to all incoming middle school students.

Summary

The burden of HPV associated cancers in Kentucky is among the highest in the country. Additionally, the rates of HPV vaccination continue to be far below the nationwide averages. Although Kentucky's initiation rates are low, this pilot study revealed an FQHC with initiation rates near HealthyPeople 2020 goals. Provider identified barriers and facilitators influenced the practice and policy implications. The most commonly reported barriers at just over 80% (n=9) were the lack of a school mandate for the HPV vaccine and the fact that patients are unlikely to return for doses 2 and 3. Objective data supported the providers' subjective data as only 34% of patients returned for dose 2 and only 8% for dose 3. Based on this, a policy initiative to increase all three ACIP adolescent vaccines was proposed to the Fayette county district health coordinator in late February. A nurse letter, principal letter and text message reminders for all 3 ACIP recommended adolescent vaccines will be initiated this spring.

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Future research could assess the impact of the school based campaign as well as the new 2-dose series. Because of the provider reported barrier of returning for doses 2 and 3, a follow-up study at the FQHC could include an assessment of completion rates with the new 2-dose regimen versus completion rates with the 3-dose regimen.

Table 1. Demographic characteristics by HPV vaccination (N=63)

	Total sample n = 63	Initiated HPV vaccination		<i>p</i>
		Yes (n =50)	No (n =13)	
Age		13.1 (2.0)	14.5 (2.1)	.024*
Sex				
Male	29 (54%)	22 (72%)	7 (18%)	>.05
Female	34 (46%)	28 (84%)	6 (22%)	
Race				
White	19 (30%)	14 (74%)	5 (26%)	>.05
Black	37 (60%)	32 (87%)	5 (13%)	
Other	6 (10%)	3 (50%)	3 (50%)	
Ethnicity				
Hispanic	39 (62%)	27 (69%)	12 (31%)	.012*
Non-Hispanic	24 (38%)	23 (92%)	1 (8%)	
Insurance				
Private	5	5 (100%)	0 (0%)	>.05
Medicaid	46	36 (78%)	10 (22%)	
Uninsured	11	9 (82%)	2 (18%)	

*significance at level $p < .05$

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Table 2. Provider Survey Results (n=11) offer vs. accept/initiate HPV vaccine

	100%	75-99%	50-74%	25-49%
How often offer HPV vaccine to females 11-17	7	3	1	0
How often offer HPV vaccine to males age 11-17	7	3	1	0
How often do females accept/initiate	0	3	8	0
How often do males accept/initiate	0	3	5	2

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Table 3. Provider reported practice facilitators (n=11)

Practice facilitators		Total
Participates in the VFC program	9	11
Have the time to educate patients about the HPV vaccine	8	11
Reminders within the EMR for the HPV vaccine	1	11
Clinic uses a form that prompts CDC recommended vaccines	2	11

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Table 4. Provider reported practice barriers (n=11)

	Yes	Total
I do not have the time to discuss HPV vaccination during visits	2	11
Practice not adequately reimbursed for HPV vaccine	1	11
HPV vaccine not stocked or in low supply	0	11

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Table 5. Provider reported patient barriers (n=11)

Unaware of the risks of HPV	4	11
Think the cost of the HPV vaccine is too high	0	11
Worried about long-term safety of the vaccine	0	11
Unlikely to return for 2nd and 3rd dose	7	11
Unlikely to get vaccine because it is not required for school entry	8	11
Concerned about the pain associated with the vaccine	1	11

Table 6. Relevant literature

Citation	Conceptual Framework	Design/Method	Sample/Setting	Major Variables Studied and Their Definitions	Outcome Measurement	Data Analysis	Findings	Level of Evidence	Quality of Evidence: Critical Worth to Practice
(Ferrer et al., 2014) Ferrer, H. B., Trotter, C., Hickman, M., & Audrey, S. (2014). Barriers and facilitators to HPV vaccination of young women in high-income countries: a qualitative	Critical Appraisal Skills Programme criteria for evaluating qualitative research	Qualitative systematic review and evidence synthesis	Sample: 41 Studies were eligible if qualitative research methods (interviews, focus groups, observations) or open-ended questions in questionnaires were used to explore views and behaviors related to decision-making of HPV vaccination of young women.	Qualitative & descriptive, so no independent/dependent variables quantified	Used a socio-ecological model to provide a framework for understanding how decisions of stakeholders at different levels of the model may affect access of the HPV vaccine for young women.	Data pertaining to the methodology and context, including study and participant characteristics of each primary study, were extracted and entered into an excel spreadsheet by one reviewer (HF).	Qualitative findings: providers were generally favorable towards HPV vaccine; some felt uncertainty about the safety profile of the vaccine and that early vaccination may mean protection would not be maintained to the age of sexual debut; Healthcare professionals suggested that parents with general 'anti-	V	Strengths: Comprehensive review of a range of perspectives resulting in a more complete picture in relation to decision-making for HPV vaccination The method of using qualitative synthesis within a socioecological framework enabled facilitators and barriers to

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ve systemat ic review and evidenc e synthesi s. <i>BMC Public Health</i> , 14, 700. doi: 10.1186 /1471- 2458- 14-700							vaccination' beliefs were unlikely to make positive HPV vaccine decisions; evidence presented here suggests that some healthcare professionals avoided conversations with parents about the HPV vaccine if they perceived this to be culturally inappropriate.		be identified in relation to different stakeholders Limitations Studies not published in English were excluded and the findings reported therefore may be subject to English language publication
(Rambo ut et al., 2014) Rambou t, L.,	None mentione d	Systemat ic review with data analysis	Sample: Twenty-two studies including 8079 females aged 9–26	Self- identified barriers and facilitators to receiving the HPV vaccine	Data abstraction form was developed a priori and pilot-tested	Descriptive synthesis of abstracted data was completed for all	The most commonly reported facilitators were perceived benefit of the	I SR of RCT's and	Strengths: First systematic review to isolate views of adolescent

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Tashkandi, M., Hopkins, L., & Tricco, A. C. (2014). Self-reported barriers and facilitators to preventive human papillomavirus vaccination among adolescent girls and young women: A systematic review. <i>Preventive Medicine</i>			years in North America, published between 2008 and 2011 Inclusion criteria: Qualitative or quantitative studies of self-reported barriers to the HPV vaccine in adolescents and young women age 9-26 (US & Canada only)		by two reviewers. Two reviewers then performed all data abstraction in duplicate.	included studies with respect to study characteristics, study outcome results, and study quality. Heterogeneity among studies precluded meta-analysis.	vaccine and receiving a recommendation from a healthcare provider, which were each reported in six of the studies. endorsement by influential others, such as parents and health care providers, appear to be important factors in prompting vaccination	cohort studies	girls and young women with respect to the acceptability of HPV vaccination. Limitations: the pooling of data from small samples of participants with differing characteristics thus limiting the ability to assess whether diverse interventions may be needed for various subgroups of young females. Applicable to practice setting because of
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e, 58, 22-32. doi: 10.1016/j.ypmed.2013.10.009									theme of influence of endorsement by healthcare provider
(Hull et al., 2014) Hull, P. C., Williams, E. A., Khabele, D., Dean, C., Bond, B., & Sanders, M. (2014). HPV vaccine use among African American girls: Qualitative	Dissemination of Innovations Theory	Design: cross-sectional observational design, Method: Focus groups and interviews	Sample: African American girls ages 11–18 (N=34) and their mothers (N=31), broken into market segments based on daughter's vaccination status and mother's intent to vaccinate Setting: convenience sampling	No IV or DV because qualitative study design	Comprehensive review of transcription data of focus groups and interviews	Four research assistants were trained during two 90-min sessions to code the transcript data, including how to use Atlas.ti qualitative analysis software to create and assign codes and extract quotes	Barriers to vaccination included no recommendation from healthcare professional Decision influencers for both mother & daughters also included a provider recommendation Recommendations from mothers: Message from trusted source; Recommend together with	VI	Strengths: This is the first published study to identify specific market segments related to HPV vaccine and to report on formative qualitative data aimed at comparing the Undecided segment to those who have received or rejected the

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<p>ve formativ e research using a participa tory social marketi ng approac h. <i>Gynecol ogic Oncolog y, 132, S13- S20. doi: 10.1016 /j.ygyno .2014.01 .046</i></p>							<p>other preteen vaccines; Information about safety/side effects; Statistics on cancer and mortality</p>		<p>vaccine. Limitations: self-reported data and convenience sampling</p> <p>Application: Data further supports the influence of provider recommenda tion for the vaccine</p>
<p>(Bynum et al., 2014) Bynum, S. A., Staras, S. A., Malo, T. L.,</p>	<p>none mentione d</p>	<p>Using Dillman Multi- phase recruitme nt approach: Surveys mailed</p>	<p>Physicians eligible for study inclusion included those who saw 25 or more 9- to 17- year-old girls in the past</p>	<p>Independent variables: physician demographi cs (age, gender, practice specialty)</p>	<p>5-point Likert scales were used in survey</p>	<p>Multivariable logistic regression was used to model the probability of recommendi ng the HPV</p>	<p>34% of physicians recommended vaccination for girls in the early (9-10 years) vaccination age group.</p>	<p>VI</p>	<p>Strengths: large random sample size</p> <p>Limitations: data were self- reported,</p>

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<p>Giuliano, A. R., Shenkm an, E., & Vadapar ampil, S. T. (2014). Factors associate d With Medicaid provider s' recomm endation of the HPV vaccine to low-income adolesce nt girls. <i>J Adolesc Health</i>, 54(2), 190-196. doi: 10.1016/j.jadohe alth.201</p>		<p>between 10/2009 and 04/2010 to a random sample of 800 Florida-based physician s serving Medicaid -enrolled adolescen ts. Data were analyzed in 2013</p> <p>A multi-item survey, adapted from a previous national study of HPV vaccinati on among physician s, was</p>	<p>year and had a primary care specialty. Of the 800 mailed surveys, 485 were completed and returned. Of those, 52 did not meet eligibility criteria. The final study sample included 433 physicians. The overall response rate was 68.3%</p>	<p>Dependent variables: rates of recommendi ng HPV vaccine</p>		<p>vaccine to adolescent girls aged 9-17.</p> <p>All analyses were conducted in 2013 using SPSS 20.0. Statistical tests were two-tailed, with alpha level of .05 and 95% confidence interval (CI) for odds ratios (OR).</p>	<p>74% of physicians recommended vaccination for 11- to 12-year-old adolescent girls. 86% of physicians recommended HPV vaccination to adolescent girls aged 13-14. Discomfort discussing STIs with parents was negatively associated with HPV vaccine recommendatio n for all groups,</p>		<p>which may have introduced recall and reporting bias.</p> <p>Feasibility of use in practice: Results of provider identified barriers can be used to aid in developmen t of intervention s to increase vaccination rates</p>
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3.08.006		used to assess barriers related to HPV vaccine recommendation							
(Bruno et al., 2014) Funding: NIH/NCI grant Bruno, D. M., Wilson, T. E., Gany, F., & Aragones, A. (2014). Identifying human papillomavirus vaccination practices	None mentioned	Cross-sectional survey of randomly selected primary care providers	Sample: 552 providers were identified and a random sample of 120 was generated 64%- Peds. 19% - internists 17% - family practitioners Setting: Brooklyn, New York between November 2010 and January 2012. Inclusion	Independent variables: Provider demographics Dependent variables: Whether or not HPV vaccine was offered; identified barriers	Survey used Likert scale responses	Data were manually entered into an access database by a research assistant and quality control was performed by the principal investigator to find and address any potential data entry problem. Analysis was performed using IBM SPSS Statistics® ver-	34% of respondents reported that they routinely offered HPV vaccine to their eligible patients. 70% of physicians reported that the lack of preventive care visits for patients in the eligible age group limited their ability to recommend the HPV vaccine and 70% of those who reported this barrier do not routinely	VI	Strengths: identifies several potential opportunities for interventions that could lead to increased HPV vaccination. Limitations: Results are all self-reported, so possibility that respondents reported socially desirable responses.

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among primary care providers of minority, low-income and immigrant patient populations. <i>Vaccine</i> , 32(33), 4149-4154. doi: 10.1016/j.vaccine.2014.05.058			criteria: pediatricians, family practitioners, and internal medicine physicians serving neighborhoods identified from the American Community Survey as having large minority populations (greater than 30%) and higher than the average rates of HPV related cancer cases according to the New York State Cancer Registry			sion 19.	recommend HPV vaccine. most common barrier impeding them from offering the vaccine was lack of time to educate parents or patients (66%).		Feasibility of use in practice: Using the identified barrier of not enough time to educate parents/patients can assist with interventions to increase patient education (i.e. the CDC HPV fact sheet for parents)
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<p>(Thomas et al., 2013)</p> <p>Funding: Robert Wood Johnson Foundation</p> <p>Thomas, T. L., Strickland, O., Diclemente, R., & Higgins, M. (2013). An opportunity for cancer prevention during preadolescence and adolescence:</p>	<p>Health Belief Model (HBM)</p>	<p>Descriptive cross-sectional design</p> <p>Method: surveys, and quantitative analysis.</p>	<p>Sample: 519 subjects (35% response rate)</p> <p>Inclusion criteria: parent or primary caregiver responsible for girls or boys aged 9 to 13 years; had to reside in the counties of interest, speak and read English, and be at least 18 years of age.</p>	<p>Independent variables: 4 constructs of the HBM</p> <p>Perceived vulnerability, perceived severity, perceived benefits, perceived barriers</p> <p>Dependent variables: Intent to vaccinate or not vaccinate</p>	<p>Likert scales</p>	<p>Descriptive statistics were calculated for all variables</p> <p>t tests and analysis of variance F tests for all continuous variables and c2 tests for all categorical variables.</p>	<p>343 (66.1%) indicated that they will not or had not vaccinated their child, 169 (32.6%) indicated that they will or had vaccinated their child, and 7 (1.3%) did not respond to this question. Focusing on perceived barriers and benefits and on parents' level of knowledge about HPV, healthcare providers can have frank conversations with parents in order to facilitate the parents' informed decision making.</p>	<p>VI</p>	<p>Strengths: Large sample cohort study with focused rural parent population</p> <p>Limitations: Very low response rate with telephone survey method, so methods were changed to paper & pencil & face to face to increase response rates. Feasibility of use in practice: This study is particularly useful for providers in</p>
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stopping human papillomavirus (HPV)-related cancer through HPV vaccination. <i>J Adolesc Health</i> , 52(5 Suppl), S60-68. doi: 10.1016/j.jadohealth.2012.08.011									a rural practice setting to provide a framework from which to design interventions to increase rates of HPV vaccination
CDC NIS data 2013 Retrieved from: http://www.cdc.gov/vaccines/who/teens/va		Design: The NIS-Teen is a random-digit-dialed telephone survey of parents and	Sample: 6,039 by landline (59.5%) and 12,225 by cell phone (54.5%) had adequate provider data	Independent variables: Demographics (age, gender, ethnicity, income-level, insurance coverage)			Nationwide HPV vaccine rates: 1-dose= 57% 2-doses=47% 3-doses=37% Kentucky's rates: 1-dose= 47%	NA	Strengths: Large sample national survey with provider verified vaccine data included

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ccination-coverage.html http://www.cdc.gov/mmwr/preview/mm6329a4.htm?_cid=mm6329a4_w#tab3		<p>guardians of teens 13–17 years old; in 2013, it included data for more than 18,000 adolescents. The telephone survey is followed by collection of vaccination records from clinicians.</p> <p>Method: random digit dial (RDD) list-assisted landline and cell-phone</p>		<p>Dependent variables: Provider verified rates of vaccination from 2013</p> <p>Parental reasons for not vaccinating</p>			<p>2-doses=38% 3-doses=26%</p> <p>Top 5 reasons parents did not initiate vaccine: Lack of knowledge=15.5% Not necessary=14.7% Safety concerns=14.2% Not recommended= 13% Not sexually active=11.3%</p>	<p>Weaknesses : response rates may mean incomplete data</p> <p>Implications Kentucky is nearly 10% points below the national level</p> <p>NO provider recommendation is 4th out of 5 on the list of barriers at 13% reported</p>
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		sample frame							
CDC HPV statistics Retrieve d from: http://www.cdc.gov/cancer/hpv/statistics/state/cervical.htm			Data from population- based cancer registries participating in the CDC's supported <u>National Program of Cancer Registries</u> or NCI's - supported Surveillance, Epidemiology, and End Results Program, includes all states meeting USCS publication criteria for all years 2006– 2010 and covers approximately 94.8% of the U.S. population.				Incidence of HPV in Kentucky 8.04- 9.54 per 100,000 Nationwide rates are	NA	Implications : KY ranks in the highest tier of cervical cancer rates in the US, so programs to increase HPV vaccine rates are validated

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(Jeudin et al., 2014) ACS grant Jeudin, P., Liveright, E., del Carmen, M. G., & Perkins, R. B. (2014). Race, Ethnicity, and Income Factors Impacting Human Papillomavirus Vaccination rates. <i>Clinical Therapeutics</i> , 36(1), 24-37.	None mentioned	Systematic review of 124 references (NIS data, RCT's)	Sample: relevant English-language literature (124 sources) to identify current vaccination rates and factors associated with vaccine uptake.	Independent variables: age, gender, ethnicity Dependent variables: rates of vaccine initiation and completion; barriers and facilitators to vaccination	Systematic review of data pertaining to outcomes of HPV vaccine rates, and identified barriers and facilitators	HPV vaccination recommendation by a health care provider has been shown to increase the likelihood of vaccination up to 18-fold (95% CI, 1–23) and up to 90% of females who report vaccination also report provider recommendation.	Provider recommendation is a key factor in HPV vaccination, and minorities are less likely to report receiving recommendations for HPV vaccination; desire to prevent cancer was also a key factor in vaccination rates	I	Strengths: Systematic review of 124 references by 4 physicians from Boston University and Harvard Limitations: The exact methods of data extraction, analysis and synthesis were not described by the authors Feasibility of use in practice: Because provider recommendation is crucial to vaccine uptake, and each provider interacts
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doi: 10.1016 /j.clinth era.2013 .11.001									with hundreds to thousands of patients, interventions targeting providers such as academic detailing or performance - improvement continuing medical education may be effective ways to improve vaccination rates.
(Gilkey, Dayton, et al., 2014b) Gilkey, M. B., Dayton, A. M., Moss, J. L.,	CDC's AFIX model for improvin g vaccinatio n rates	Randomi zed- controlle d trial	Sample: randomly assigned 91 primary care clinics in North Carolina, serving 107,443 adolescents, to	Independent variables: IV1 = in- person AFIX consultation IV2 = webinar consultation IV3 = no	Primary study outcome was 5- month coverage change for Tdap, meningococc al vaccine,	x2 (Chi- squared) tests and analysis of variance models were used. To analyze intervention effects at the	Among adolescents ages 11 to 12 years, AFIX consultations increased coverage for the 3 vaccines in the	II	Strengths: statistical significance found at the 5-month follow-up in the 2 intervention arms

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<p>Sparks, A. C., Grimshaw, A. H., Bowling, J. M., & Brewer, N. T. (2014). Increasing Provision of Adolescent Vaccines in Primary Care: A Randomized Controlled Trial. <i>Pediatrics</i>, 134(2), E346-E353. doi: 10.1542/peds.20</p>			<p>receive 1. no consultation 2. an in-person or 3. webinar AFIX consultation.</p> <p>Inclusion criteria: pediatric and family practice clinics with > 200 patients ages 11 to 18 years with active records in the registry;</p>	<p>consultation</p> <p>Dependent variables:</p> <p>Rates of adolescent vaccinations at 5 mo. Follow-up and at 1 year</p>	<p>and HPV vaccine initiation (>1dose, female patients only); also analyzed coverage changes for other vaccines at 5 months and for all outcomes at 1 year.</p>	<p>level of the patient, authors performed mixed-level Poisson regressions for each vaccine, modeling the change in vaccine coverage between baseline and follow-up for each age group.</p>	<p>adolescent platform at 5 months</p> <p>In-person arm rate increases:</p> <p>Tdap (3.4%) MCV (4.7%) HPV (1.5%)</p> <p>Webinar arm:</p> <p>Tdap (3.6%) MCV (4.4%) HPV (1.9%)</p> <p>adolescents 13 to 18 years, AFIX consultations increased vaccine coverage at 5 months only for the in-person versus control arms for HPV vaccine series completion (0.7%).</p>	<p>Limitations: no statistical significance found in intervention arms at 1-year may indicate that vaccine providers in the intervention arms were able to initiate, but not sustain, quality improvement efforts</p> <p>Feasibility of use in practice: This study has direct correlation to support program planning using the AFIX model</p>
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13-4257									
(Reiter et al., 2014)	secondary data analysis of publicly available data from the NIS-Teen	analyzed provider-verified vaccination data from the 2010–2011 National Immunization Survey-Teen for Hispanic females ages 13 to 17 years (n =2,786).	<p>Sample: Hispanic adolescent females age 13-17; N= 2786</p> <p>Setting: 2010-2011 NIS data from the CDC</p>	<p>Independent variables: ethnicity, age & gender</p> <p>Dependent variables: rates of vaccination; determinants of vaccination</p>	<p>Rates of vaccination as reported by the NIS data</p> <p>Correlates of HPV vaccination identified in NIS data</p>	weighted logistic regression to identify correlates of HPV vaccine initiation	Healthcare provider recommendation was one of the key determinants of HPV vaccination among Hispanic adolescent females. HPV vaccine initiation was 60.9%, completion was 36.0%, and follow-through was 59.1%. Initiation and completion were more common among older daughters and	IV	<p>Strengths = large cohort (2736) of respondents</p> <p>Limitations = focused on Hispanic population</p> <p>Applicable to practice setting because provider recommendation was again an identified key determinant to HPV vaccine initiation</p>

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							those whose parents had received a provider recommendation to vaccinate (all $P < 0.05$). Spanish-speaking parents were more likely to indicate lack of provider recommendation (20.2% vs. 5.3%)		
<p>**(Moss, Reiter, Dayton, & Brewer, 2012b) Moss, J. L., Reiter, P. L., Dayton, A., & Brewer, N. T. (2012a).</p>	<p>CDC's AFIX model</p>	<p>A one-month immunization competition among federally qualified health centers, during April 2010. Participation was</p>	<p>clinical coordinators from 17 federally qualified health centers (serving 7827 patients ages 12–17) in North Carolina participated in a competition to increase uptake of adolescent</p>	<p>Rates of recommended adolescent vaccines: tetanus, diphtheria, and pertussis booster; meningococcal conjugate; and human papillomavirus.</p>	<p>Rates of adolescent vaccine coverage</p>	<p>Data analyses used SAS Version 9.2 (Cary, NC). Statistical tests were two-tailed with a critical alpha of .05.</p>	<p>Vaccine uptake increased over the one-month follow-up period ($p < .001$, Table 2). Prior to the intervention, 31.1% (IQR, 13–33%) of each clinic's adolescent population was up-to-date on targeted</p>	<p>VII</p>	<p>Strengths: A strength of this study is the use of web-based technology to administer the AFIX intervention components. While studies have shown that the AFIX program has</p>

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Increasing adolescent immunization by webinar: A brief provider intervention at federally qualified health centers. <i>Vaccine</i> , 30(33), 4960-4963. doi: 10.1016/j.vaccine.2012.05.042		open to all of the 131 federally qualified health centers in the state, and 18 clinics opted to participate in an AFIX webinar	vaccines				and non-targeted vaccines, while after the intervention, 32.2% (IQR, 14–34%) was up-to-date (Chi-square = 27.34, $p < .001$).		relatively low costs], employing webinars and emails reduces the costs associated with in-person visits. Limitations: did not have a control arm, as this would not have been acceptable to the community partners; however, the use of an instrumental comparison (non-targeted vaccines) allowed authors to treat clinics as their own
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									controls.
<p>**(LeBaron et al., 1999b) LeBaron, C. W., Mercer, J. T., Massoudi, M. S., Dini, E., Stevenson, J., Fischer, W. M., . . . DesVignes-Kendrick, M. (1999). Changes in clinic vaccination</p>	AFIX model	Retrospective examination of clinic vaccination coverage data	Children aged 19 to 35 months enrolled in clinics in localities that had applied the intervention for 4 years or longer.	Four states and 2 cities that had applied the AFIX intervention for 4 years or longer were identified. The number of clinic records reviewed annually was 4639 to 18,000 in 73 to 116 clinics for states, and 714 to 5276 in 8 to 25 clinics for cities.	Change in median clinic coverage rates, based on the primary (4-3-1) vaccine series, with comparison to results of the National Immunization Survey.	Authors used same method as in Georgia Distribution plot by rank ordering all clinics in a locality by coverage rate, plotting this distribution in deciles and determining the median	Median clinic coverage rose in all localities: Missouri, 44% (1992) to 93% (1997); Louisiana, 61% (1992) to 83% (1997); Colorado, 55% (1993) to 75% (1997); Iowa, 71% (1994) to 89% (1997); Boston, Mass, 41% (1994) to 79% (1997); and Houston, Tex, 28% (1994) to 84% (1997). The increase in clinic coverage exceeded that of the general population in 5	IV	<p>Strengths: Average vaccine rate increase of 5% over 4-years was very close to the 6% increase seen in the Georgia state 7 year study. Demonstrate reproducibility of positive effects</p> <p>Limitations: the clinics measured began collecting vaccination data and</p>

<p>**(LeBaron et al., 1997) LeBaron, C. W., Chaney, M., Baughman, A. L., Dini, E. F., Maes, E., Dietz, V., & Bernier, R. (1997). Impact of measurement and feedback on vaccination coverage in public clinics, 1988-1994. <i>Jama</i>, 277(8), 631-635.</p>	<p>None mentioned</p>	<p>Examination of data from Georgia public clinics, doses-administered records, and National Health Interview Surveys.</p> <p>ITS based</p>	<p>Children attending Georgia public clinics.</p>	<p>Vaccination coverage rates</p>	<p>For the period 1988 through 1994, 136 004 Georgia public clinic vaccination records for children 21 to 23 months of age were reviewed.</p>	<p>Basic statistical analysis (medians, ranges)</p>	<p>Median series-completion rates at public clinics rose from 53% to 89%, while indexes of under-vaccination fell: missed opportunities for simultaneous vaccination (6% to 0%), lost contact for more than 12 months (14% to 1%), and first vaccination more than 1 month late (19% to 8%) In 1988, vaccination coverage of children 24 months of age in the National Health Interview Survey (NHIS) was 53%, identical to median public clinic coverage in Georgia; in 1993, NHIS coverage was 60%, while median public clinic coverage in Georgia was 90%,</p>	<p>IV</p>	<p>Study shows widespread application of the AFIX program with measurable increases in vaccination rates</p>
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<p>**(Perkins, 2014)</p> <p>Perkins, R. B., Zisblatt, L, Legler, A., Trucks, E., Hanchate, A. and Gorin, S.S. (2014). Effectiveness of a provider-focused intervention to improve HPV vaccination rates in boys and girls,. <i>Vaccine, In press.</i></p>	<p>None mentioned</p>	<p>RCT</p> <p>Provider-focused intervention that included repeated contacts, education, individualized feedback, and strong quality improvement incentives to raise HPV vaccination rates at two federally qualified community health centers.</p>	<p>Sample: 13, 118 eligible patients from 8 clinics</p> <p>2 clinics and 4093 patients randomly chosen for intervention arm</p> <p>Control arm was remaining 6 clinics with 9025 eligible patients</p>	<p>Assessment of baseline HPV vaccine rate</p> <p>Independent variable: Intervention arm or non-intervention arm</p> <p>Dependent variable: Number initiating HPV vaccine and completing subsequent dose due</p>	<p>HPV Vaccination rates of patients age 11-21</p>	<p>multivariable logistic regression, controlling for clustering by practice</p> <p>All analyses were performed using Stata Version 10.1.</p>	<p>During the active period, girls at intervention practices were more likely to initiate HPV vaccination than those at control practices (OR 1.6 95% CI 1.1–2.2), , differences between intervention and control practices did not remain significant in the post-intervention period.</p> <p>For vaccine-naïve boys, the odds of initiating HPV vaccination were similar at intervention and control practices in the</p>	<p>II</p>	<p>Strengths: this study demonstrates the ability of a provider-centered multi-component PI CME intervention to create sustained improvement in HPV vaccination rates. All practices improved over time, especially for boys, but intervention practices demonstrated improvements beyond those seen in control practices</p> <p>Limitations: The dramatic</p>
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		Interventions included six to eight sessions conducted over approximately 12 months.					pre-intervention period. The odds of vaccine initiation among boys at intervention compared to control practices rose to 11 (95% CI 6.9–18) in the transition period, 11 (95% CI 6.9–17) in the active period, and remained elevated at 8.5 (95% CI 5.2–14) in the post-intervention period		improvements in HPV vaccination rates for boys were catalyzed by the availability of state-funded HPV vaccine for boys during the transition period, making the effects of the intervention difficult to distinguish from the effects of increased vaccine availability Applicability to practice: The authors utilized the AFIX model for their intervention and achieved
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									measurable improvements in HPV vaccine rates in a large population
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Key Terms and Abbreviations:

AFIX = Assessment, Feedback, Information and Exchange

Tdap = Tetanus, diphtheria and pertussis vaccine

CDC = Centers for Disease Control

CI = Confidence Interval

DV = Dependent variable

HPV = Human Papillomavirus

IV = Independent variable

ITS = Interrupted time series study

MCV = Meningococcal vaccine

NIS = National Immunization Survey

RCT = Randomized controlled trial

SR = Systematic review

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Table 7. Level of Evidence Synthesis Table

	1	2	3	4	5	6	7	8	9	10	11	12	13
Level I: Systematic review (SR) or meta-analysis	X	X											
Level II: Randomized Controlled Trial (RCT)			X	X									
Level III: Controlled trial without randomization													
Level IV: Case-control or cohort study					X	X	X						
Level V: SR of qualitative or descriptive studies								X					
Level VI: Qualitative or descriptive study									X	X	X	X	
Level VII: Expert opinion or consensus													X

Key to Synthesis table

1 - (Jeudin et al., 2014) 2 - (Rambout et al., 2014) 3 - (Gilkey, Dayton, et al., 2014b) 4 - (Perkins, 2014)
5 - (LeBaron et al., 1997) 6 - (LeBaron et al., 1999b) 7 - (Reiter et al., 2014) 8 - (Ferrer et al., 2014)
9 - (Bruno et al., 2014) 10 - (Bynum et al., 2014) 11 - (Hull et al., 2014) 12 - (Thomas et al., 2013) 13 - (Moss et al., 2012a)

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Table 8. Evaluation Methods

Evaluation Methods	Measures (Level of Measure)	Data Source	Data Collection Plan	Timeline	Type of Evaluation	Type of Data Analysis
Objective 1 To increase numbers of HPV vaccination among adolescents 11-17	Proportion of HPV vaccination in 11-17 year olds (count)	EMR Query	Pre - intervention	Baseline rates (December 2015- February 2016)	Outcome	Chi-square analysis
Specific Aim 1: 80% of providers utilize CDC rubric when presenting the HPV vaccine	Number of provider respondents indicating regular use of CDC rubric (count)	Provider Survey	Pre- and post-intervention survey	December, 2016 – February 2017	Process	Percentages & frequencies Chi-squared analysis
Specific Aim 2: 80% of adolescents initiate 3 dose HPV series.	Proportion of HPV vaccination in 11-17 year olds (count)	EMR Query	Post-intervention	Post Intervention rates (December 2016 – February 2017)	Outcome	Chi-square analysis

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Appendix A. Chart Audit Tool

Study number:_____

Gender:_____

Age:_____

Race:_____

Insurance:_____

At the patient's 11-17 year old well-child visit, were the following documented:

Information	Yes	No	Comments
Was counseling on the HPV vaccine provided?	By: ____ CMA ____ NP/MD		
Was the HPV vaccine offered?			
Patient's response if vaccine was offered	__ Accepted __ Deferred __ Declined		
Was the HPV vaccine series initiated?			
Was the vaccine series initiated or completed prior to this visit?			
Were the other ACIP recommended vaccines (Tdap & MCV) given?			

Doses given (Y/N)? #1_____ #2_____ #3_____

On-time? Y/N Y/N Y/N

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Appendix B. Provider Survey/Questionnaire

Please answer the following questions by selecting the answer that best represents your experience as a provider:

1. How often do you offer the HPV vaccine during routine well-child exams for 11-12 year old FEMALES?

<input type="checkbox"/>	100%	<input type="checkbox"/>	25-49%
<input type="checkbox"/>	75-99%	<input type="checkbox"/>	0-25%
<input type="checkbox"/>	50-74%		

2. How often do you offer the HPV vaccine during routine well-child exams for 11-12 year old MALES?

<input type="checkbox"/>	100%	<input type="checkbox"/>	25-49%
<input type="checkbox"/>	75-99%	<input type="checkbox"/>	0-25%
<input type="checkbox"/>	50-74%		

3. When offered, what percentage of your FEMALE patients accept HPV vaccination:

<input type="checkbox"/>	100%	<input type="checkbox"/>	25-49%
<input type="checkbox"/>	75-99%	<input type="checkbox"/>	0-25%
<input type="checkbox"/>	50-74%		

4. When offered, what percentage of your MALE patients accept HPV vaccination:

<input type="checkbox"/>	100%	<input type="checkbox"/>	25-49%
<input type="checkbox"/>	75-99%	<input type="checkbox"/>	0-25%
<input type="checkbox"/>	50-74%		

Which of these factors affect your decision to recommend the HPV vaccine in your current practice? Please select all that apply:

Practice Facilitators		Practice Barriers	
<input type="checkbox"/>	My practice participates in the Vaccines for Children (VFC) program.	<input type="checkbox"/>	The HPV vaccine is not stocked or there is low availability in my practice.
<input type="checkbox"/>	My clinic has reminders within the EMR for HPV vaccination.	<input type="checkbox"/>	My practice is not adequately reimbursed for HPV vaccine administration.
<input type="checkbox"/>	My clinic uses a form during well-child exams that prompts for CDC recommended vaccinations.	<input type="checkbox"/>	I do not have time to discuss HPV vaccination during patient visits.
<input type="checkbox"/>	I have time to educate my patients about HPV and the vaccine.	Other:	
Other:			

Continued on next page.....

Which of these factors affect your decision to recommend the HPV vaccine in your current practice? Please select all that apply:

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Provider Facilitators		Provider Barriers	
	I strongly recommend the HPV vaccine to all eligible patients.		I have concerns about the long-term safety of the HPV vaccine.
	I have completed continuing education regarding HPV and/or the HPV vaccine.		I feel uncomfortable discussing a vaccine for a sexually transmitted infection with my patients and/or their parents.
	I am aware of the CDC/ACIP recommendations for HPV vaccination.		I do not agree with the CDC/ACIP recommendations for HPV vaccination.
Other:		Other:	

Patient Facilitators		Patient Barriers	
	My patients have a good understanding of the risks of HPV infection.		My patients are unaware of the risks of HPV infection.
	My patients/their parents believe that they are at risk for HPV.		My patients think the cost of the HPV vaccine is too high.
	My patients have a belief in primary prevention.		My patients are worried about the long-term safety of the HPV vaccine.
	My patients are aware of the Vaccines for Children (VFC) program and its coverage.		My patients are unlikely to return for the 2 nd and 3 rd dose of the vaccine series.
	My patients have positive peer/family support regarding HPV vaccination.		My patients are unlikely to get the vaccine because it is not required for school entry.
Other:			My patients are concerned about the pain associated with the HPV vaccine.
		Other:	

Please answer the following questions about the CDC/ACIP recommendations for HPV vaccination to the best of your knowledge:

8. What is the recommended interval for HPV vaccination? Check all that apply

- a. 0, 3, and 6 months
- b. 0, 1-2, and 6 months
- c. 0, and 6-12 months
- d. 0, 6, and 9 months

Continued on next page...

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9. What is the ideal age of vaccination for males and females?

- a. ages 11-12, can be given as early as 9
- b. ages 13-15, can be given as early as 11
- c. ages 9-13, can be given as early as 9
- d. ages 15-18, can be given as early as 9

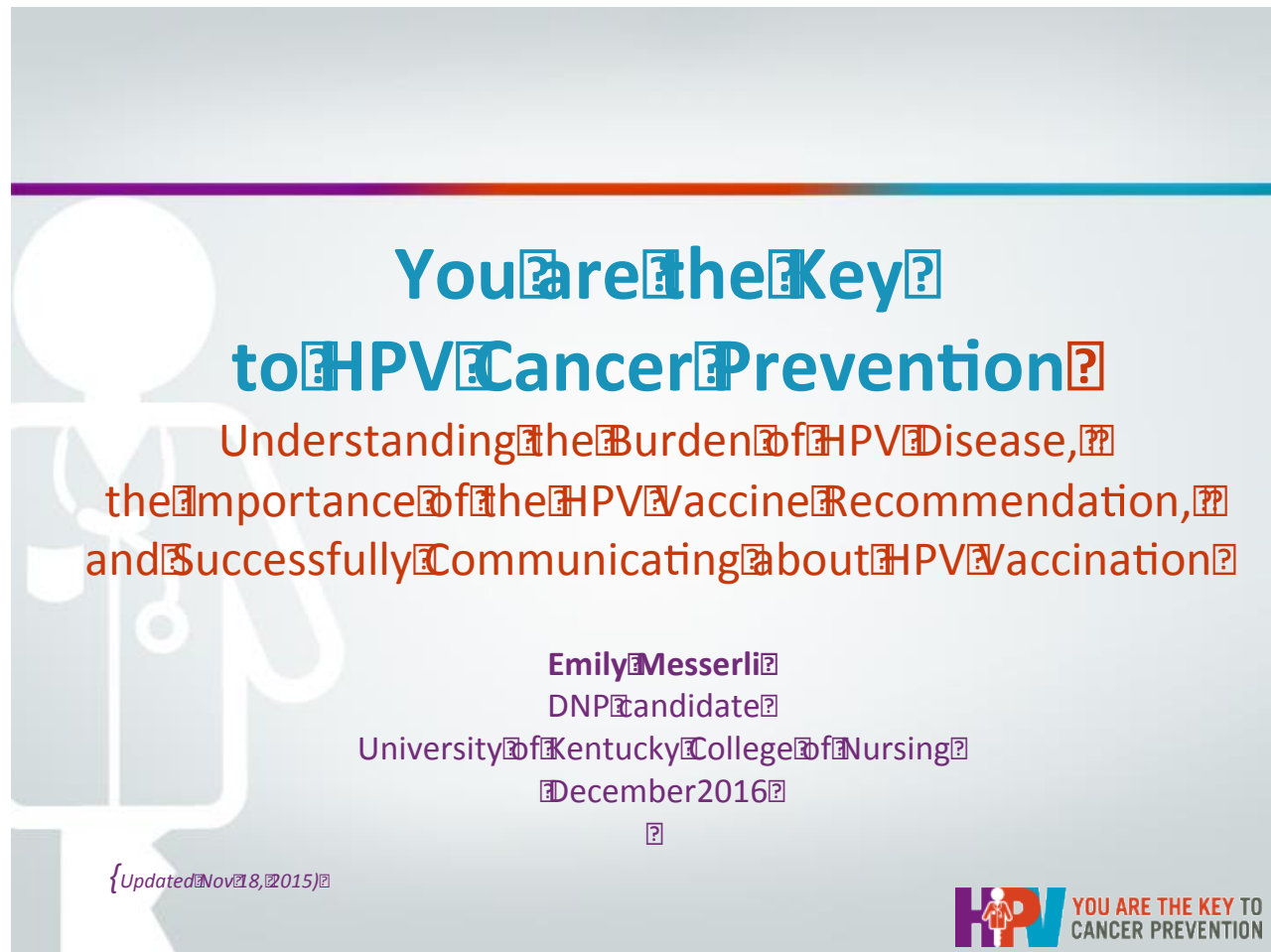
10. What are the recommendations for catch-up vaccination for males and females?

- a. Catch-up for unvaccinated men and women ages 13-18.
- b. Catch-up for unvaccinated men and women ages 13-21.
- c. Catch-up for unvaccinated men ages 13-21 (and up to 26 for special populations), catch-up for women 13-26.
- d. Catch-up for unvaccinated men ages 15-21 (and up to 26 for special populations), catch-up for women 15-26.

Comments: Please feel free to share any comments or ideas you have related to the HPV vaccine recommendations for 11-12 year olds in your clinic...

THANK YOU FOR PARTICIPATING!

Appendix C. CDC slide set on HPV vaccine



You are the Key to HPV Cancer Prevention

Understanding the Burden of HPV Disease, the Importance of the HPV Vaccine Recommendation, and Successfully Communicating about HPV Vaccination

Emily Messerli
DNP candidate
University of Kentucky College of Nursing
December 2016

{Updated Nov 18, 2015}

HPV YOU ARE THE KEY TO CANCER PREVENTION

Appendix D. Provider talking tips rubric

Addressing Parents' Top Questions about HPV VACCINE

Recommend the HPV vaccine series the same way you recommend the other adolescent vaccines. Try saying, "Your child is due for vaccinations today to help protect against meningitis, HPV cancers, and pertussis. We'll give those shots at the end of the visit."

Parents may be interested in vaccinating, yet still have questions. Some parents might just need additional information from you, the clinician they trust. Taking the time to answer their questions and address their concerns can help parents accept HPV vaccination when their child is at the recommended ages of 11 or 12 years.

WHEN PARENTS SAY:

TRY SAYING:

Why does my child need the HPV vaccine?

HPV vaccine is important because it prevents cancer. That is why I recommend that your daughter/son be vaccinated today.

What diseases are caused by HPV?

Certain HPV types can cause cancer of the cervix, vagina, and vulva in females, cancer of the penis in men, and in both females and males, cancers of the anus and the throat. We can help prevent infection with the HPV types that cause these cancers by starting the HPV vaccine series for your child today.

Is my child really at risk for HPV?

HPV is a very common and widespread virus that infects both females and males. We can help protect your child from the cancers and diseases caused by the virus by starting HPV vaccination today.

Why do they need HPV vaccine at such a young age?

HPV vaccination works best at the recommended ages of 11 or 12 years.

I have some concerns about the safety of the vaccine—I keep reading things online that says HPV vaccination isn't safe. Do you really know if it's safe?

I know there are stories in the media and online about vaccines, and I can see how that could concern you. However, I want you to know that HPV vaccine has been carefully studied for many years by medical and scientific experts. I believe HPV vaccine is very safe. Vaccines, like any medication, can cause side effects. With HPV vaccination this could include pain, swelling, and/or redness where the shot is given, or possibly headache. Sometimes kids faint when they get shots and they could be injured if they fall from fainting. We'll protect your child by having them stay seated after the shot.

Could HPV vaccine cause my child to have problems with infertility?

There is no data available to suggest that getting HPV vaccine will have an effect on future fertility. However, women who develop cervical cancer could require treatment that would limit their ability to have children.

I'm just worried that my child will perceive this as a green light to have sex.

Numerous research studies have shown that getting the HPV vaccine does not make kids more likely to be sexually active or start having sex at a younger age.

How do you know if the vaccine works?

Ongoing studies are showing that HPV vaccination works very well and has decreased HPV infection, genital warts, and cervical precancers in young people in the years since it has been available.

Why do boys need HPV vaccine?

HPV infection can cause cancers of the penis, anus, and throat in men and it can also cause genital warts. HPV vaccine can help prevent the infection that lead to these diseases.

Would you get HPV vaccine for your kids?

Yes, I have given HPV vaccine to my child (or grandchild, etc) because I believe in the importance of this cancer-preventing vaccine. The American Academy of Pediatrics, the American Academy of Family Physicians, cancer centers, and the CDC, also agree that getting the HPV vaccine is very important for your child.



DISTRIBUTED BY:

HPV VACCINE
IS CANCER PREVENTION

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Appendix E – proposed 5th grade school letter with 6th grade health requirements (Principal)

Dear Parent/Guardian, Your student will be enrolling in the 6th grade next year and will need the following on file prior to starting school. Per 902 KAR 2:060 a student cannot attend school without this documentation.

1. A school **Physical Examination** is **required** for 6th grade entry.

(Done within one calendar year of enrollment. *The KHSAA Sports Physical Form & Consent is a different form and **cannot** be substituted.*)

2. A current, updated **Kentucky Immunization Certificate**, including all previously **required** immunizations and the following 6th grade requirements.

* One dose of **Tdap** regardless of interval since last dose of Tetanus-containing vaccine will be required for students at 6th grade entry, with option of **Td** for individuals who cannot receive Pertussis-containing vaccine.

* Two **(2)** doses **Varicella** or proof of history of Chicken Pox. (Proof of Chicken Pox (Varicella) disease in lieu of immunization must now be in the form of a diagnosis of typical Varicella disease or verification of a history of Varicella disease or Herpes Zoster disease by a *healthcare provider*.)

* One dose of Meningococcal vaccine (**MCV**) for 6th grade entry. The use of Meningococcal Conjugate Vaccine is preferred, but Meningococcal Polysaccharide Vaccine (MPSV) may be used if the conjugate vaccine is unavailable.

6th grade recommended vaccines:

- **HPV** vaccine is recommended for preteens at age 11 or 12 to **protect against cancers and other diseases caused by HPV infection**. Both boys and girls should receive 2 doses of HPV vaccine to protect against these serious diseases. Your preteen should receive the second dose 6-12 months after the first dose.

3. If your student is going to play sports in middle school, they will need a **KHSAA Sports Physical Form & Consent** completed by you and your *Healthcare Provider*. The form is available online through www.fcps.net

Please return your student's forms as soon as you've had the appointment with your Healthcare Provider. If you complete these requirements over the summer, please bring the forms to your student's middle school prior to the first day of school.

Thanks for your help with getting your student's required 6th grade documentation turned in.

School Principal Date

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Appendix F. School Nurse Letter

[INSERT NURSE NAME], School Nurse
[INSERT SCHOOL ADDRESS]

[INSERT CURRENT DATE]

Dear Parent or Guardian:

As your child's school nurse, I want to remind you of the importance of getting your son or daughter vaccinated before they go back to school this fall. Vaccines are the best way you can protect your child from a number of serious diseases, including cancers caused by HPV.

As you are making your back-to-school checklist for your preteen, I encourage you to make sure your sons and daughters get all the vaccines that are recommended for them. Schedule your child's appointment today to ensure they are up-to-date on the vaccines they need. The Centers for Disease Control and Prevention (CDC) and the Advisory Committee on Immunization Practices recommend your son or daughter receive the following vaccines:

- Quadrivalent **meningococcal** conjugate vaccine is recommended for preteens at age 11 or 12 for protection against bacteria that cause meningococcal disease, a very serious illness which can lead to death in as little as 48 hours. A second shot is recommended for teens at age 16 to continue providing protection.
- **HPV vaccine** is recommended for preteens at age 11 or 12 to protect against cancers and other diseases caused by HPV infection. Both boys *and* girls should receive 2 doses of HPV vaccine to protect against these serious diseases. Your preteen should receive the second dose 6-12 months after the first dose.
- One dose of **Tdap vaccine** is recommended for preteens at age 11 or 12 to continue providing protection against tetanus, diphtheria, and pertussis (whooping cough).
- Preteens and teens should also get the flu vaccine every year, ideally as soon as the vaccine is available.

Kentucky requires Meningococcal and Tdap for school entry; to learn more about state immunization requirements, go to: www.immunize.org/laws.

Protect your preteen and talk with your child's clinician about what vaccines they need. You may also contact me with any questions. I can be reached at [PHONE NUMBER] and I am in my office [INSERT OFFICE HOURS FOR VISITS]. I can also provide you with additional resources about vaccination and other health topics for the preteen and teen years. To learn more about adolescent vaccines, please visit CDC's Vaccines for Preteens and Teens website at www.cdc.gov/vaccines/teens.

Sincerely,

[INSERT NAME OF SCHOOL NURSE]

Your School Nurse

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